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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/485,245

Applicant(s)
Hopkins, A

Examiner
CB Wilder

Group Art Unit
1655



☒ Responsive to communication(s) filed on May 11, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-6 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-6 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicant's amendment of claims 2, 4 and 5 in Paper No. 5 has been entered.

Title

2. The title of the invention is not descriptive. a new title is required that is clearly indicative of the invention to which the claims are directed. The instant claims are drawn to compositions comprising random mixtures of oligonucleotides and their use for labeling nucleic acids.

Objections

3. The specification and claims are objected to because of the following informalities:
 - (a) The word "stabiliser" is misspelled in claim 2 and in the specification at page 3, line 2, page 4, line 1 and page 5, line 1. It is suggested changing "stabiliser" to "stabilizer".
 - (b) The word "hybridisation" is misspelled in the specification at page 1, line 17. It is suggested changing "hybridisation" to "hybridization".
 - (c) The word "lyophilisation" is misspelled in the specification at page 4, line 12 and page 10, line 12. It is suggested changing "lyophilisation" to "lyophilization".
 - (d) The word "visualised" is misspelled in the specification at page 5, line 3. It is suggested changing "visualised" to "visualized".

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(e) The word "hybridised is misspelled in the specification at page 10, line 16. It is suggested changing "hybridised" to "hybridized".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 5 is confusing at "which method comprises" because of improper grammar. It is suggested changing "which" to "wherein the".

(b) Claim 5 and 6 are indefinite as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are actual method steps of making labeled probes as per the specification at page 7 and a concluding step resulting in the end product. Clarification is required.

(c) Claim 6 lacks proper antecedent basis for "the random mixture" because claim 5 does not recite any "random mixtures of oligonucleotides".

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Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1 and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Stratagene (January 1997). Regarding claim 1, Stratagene teaches a labeling composition comprising a random mixture of oligonucleotides which are 7 to 8 mers, said composition present in a dry state (page 274, lines 1-5 and section subheading "Linkers" and page 275, section subheading "Adapters").

Regarding claim 4, Stratagene teach wherein the composition is present in a freeze-dried state. (page 274, line 5). Therefore the claimed invention of claims 1 and 4 are anticipated by the reference of Stratagene.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 2, 3, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stratagene as applied to claims 1 and 4 above in view of Sukanuma et al. (Analytical Biochemistry January 20, 1995), and further in view of Shen et al (EP 0 726 310 August 14, 1996). Regarding claim 2, Stratagene teaches a labeling composition which are 7 to 8-mers or greater and wherein the composition is present in a dry state. Sukanuma et al. also teach a labeling composition comprising a random mixture of oligonucleotides which are 5 mers to 11 mers (page 605, col. 2, lines 36 and 37). Sukanuma et al. teach wherein the composition further comprise a polymerase enzyme, a supply of nucleotides for chain extension, a labeled nucleotide and buffer (page 606, lines 1-10). The composition of Stratagene and Sukanuma et al. differ from that of the claimed invention in that the references do not teach wherein a dye and/or stabilizer is added to the composition. In a composition similar to that of Sukanuma et al., Shen et al. teach wherein the composition is present in a dry state. Shen et al. also teach wherein the composition comprise a stabilizer along with a polymerase enzyme and a supply of nucleotides for chain extension (page 6, lines 3-7 and 22). Shen et al. do not expressly teach the incorporation of a dye. However, the use of dyes as labeling agents was routinely practiced in the art. It would have been **prima facie** obvious to one of ordinary skill in the art to add a stabilizer to the composition of Stratagene and Sukanuma et al. because the skilled artisan would have been motivated to incorporate a stabilizer to the labeling composition with a reasonable expectation of success by the teaching of Shen et al. that a stabilizing agent prevents or delays the loss of a composition's biological activity as a result of storage over time (page 4, lines 8-10). The skilled

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artisan would have been motivated further to add a dye for labeling in view of routine art practice for the obvious benefit of visualizing a polynucleotide generated with the composition.

Regarding claim 3, Suganuma et al. teach, wherein the random mixture is of 6 mer oligonucleotides (page 605, col. 2, lines 36 and 37).

Regarding claim 5, Suganuma et al. in view of Stratagene teach a method of making a labeled probe for a nucleic acid template, wherein the method comprises incubating the nucleic acid template under chain extension conditions with the labeling composition of claim 1 (bottom of page 605, beginning at line 38 to page 606, lines 11-11).

Regarding claim 6, Stratagene teach wherein the random mixture of oligonucleotides is present at a concentration of about 1 O.D./ml to 10 O.D./ml (page 274, line 2 and line 29 subheading "Contents").

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the Exr. should be directed to Exr. Cynthia Wilder whose telephone number is (703) 305-1680. The Exr. can normally be reached on Monday through Thursday from 7:00 am to 5:00 pm.

If attempts to reach the Exr. by telephone are unsuccessful, the Exr.'s supervisor, W Gary Jones, can be reached at (703) 308-1152. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed the Group's receptionist whose telephone number is (703) 308-0196.

Cynthia B. Wilder, Ph.D.

S. Etom

July 14, 2000